



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵: A61B 17/00	A1	(11) International Publication Number: WO 94/20027 (43) International Publication Date: 15 September 1994 (15.09.94)
<p>(21) International Application Number: PCT/US94/02570</p> <p>(22) International Filing Date: 9 March 1994 (09.03.94)</p> <p>(30) Priority Data: 08/028,281 9 March 1993 (09.03.93) US</p> <p>(71) Applicant: CHIRON VISION CORPORATION [US/US]; 9342 Jeronimo Road, Irvine, CA 92718-1903 (US).</p> <p>(72) Inventors: REICH, Cary, J.; 26502 Dapple Green, Laguna Hills, CA 92653 (US). MENDELSON, Todd, A.; 160 Donna Court, Anaheim, CA 92807 (US). STONE, Bradley, S.; 2521 W. Sunflower, Santa Ana, CA 92704 (US). ORCHOWSKI, Michael, W.; 1081 Skyline Avenue, Laguna Beach, CA 92651 (US). SULLIVAN, Robert, J.; 15 Flomamar, Rancho Santa Margarita, CA 92688 (US). NIGAM, Alok; 21381 Bird Hollow Dr, Trabuco Canyon, CA 92679 (US).</p> <p>(74) Agents: KRIEGER, Paul, E. et al.; Pravel, Hewitt, Kimball & Krieger, 10th floor, 1177 West Loop South, Houston, TX 77027-9095 (US).</p>		<p>(81) Designated States: AT, AU, BB, BG, BR, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KG, KP, KR, LK, LU, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, UA, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>
<p>(54) Title: APPARATUS AND METHOD FOR PREPARING AN INTRAOCULAR LENS FOR INSERTION</p>		
<p>(57) Abstract</p> <p>The apparatus has an elongated compression chamber (10) with a longitudinal passageway, having an inner surface. A portion of the passageway adjacent to the proximal end of the chamber forms a loading area (20) in which the passageway gradually decreases in size for causing an IOL (12) to be deformed or compressed as the IOL is moved along the passageway. A staging area (34) having a top and bottom wall communicates with the loading area with the passageway walls including alignment ridges or slots (40) for retaining the IOL in a deformed or compressed condition. A portion of the passageway is sized to retain the IOL in the deformed or compressed condition. The passageway includes an opening and a slot (36) or groove for permitting easy withdrawal of the forceps used for pushing the IOL through the loading area and into the staging area.</p> <div data-bbox="792 1129 1429 1900" data-label="Image"> </div>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

- 1 -

TITLE: APPARATUS AND METHOD FOR PREPARING AN
INTRAOCULAR LENS FOR INSERTION

SPECIFICATION

This is a continuation-in-part application of prior, co-pending U.S. patent application Serial No. 08/028,281, filed March 9, 1993, and incorporated herein by reference.

5 Background of the Invention

The present invention relates to intraocular lenses (IOLs) formed of a material such as silicone or a hydrogel that allows the lens to be folded, rolled or otherwise deformed or compressed and, more particularly, an improved apparatus and method for
10 deforming or compressing IOLs of that type and positioning them for insertion into the eye of a patient.

IOLs were developed a number of years ago to
15 replace a clouded natural lens, called a cataract. Cataracts cause individuals to lose their sight, either partially or completely, because clouding prevents light and an image from being transmitted through the lens onto the retina. When the clouding
20 becomes severe, an individual can no longer see.

- 2 -

Replacement of the natural lens with an IOL has become an accepted procedure for alleviating the symptoms of a cataract.

Various surgical procedures have been developed
5 for removing a cataract, ranging from physically
lifting the lens from the membrane that encapsulates
the lens to emulsifying the lens through the use of
sound waves and suction equipment. It has been
found that this latter procedure, known as
10 phacoemulsification, is advantageous because a much
smaller incision is required in the eye, 3 mm or
smaller, than other techniques where the lens is
removed intact. A smaller incision is desirable
because if sutures are used to close it, the eyeball
15 is deformed less than for larger incisions which are
typically up to 6.5 - 8 mm. Further, with incisions
under 3 mm, sutures are generally not required and
the incision heals itself. The lack of sutures
offers an even further assurance that the ocular
20 globe or eyeball will not be deformed.

A number of different attempts have been made
to develop IOLs which can be inserted through the
smaller incision openings. Before the availability
of IOLs formed of a soft material that could be
25 deformed or compressed, various techniques were
attempted to develop a small profile IOL, ranging
from forming lenses with a narrower lateral
dimension to various types of lenses that could be
dismantled or manipulated and rebuilt in the eye.

30 After IOLs formed of silicone or a hydrogel
material became available, IOLs could be folded,

- 3 -

rolled or otherwise deformed or compressed so that they could be inserted into the eye through a much smaller incision than previously possible. Such lenses are described and shown, for example, in U.S. patent 4,573,998 to Mazzocco.

Various techniques and equipment have been developed for folding soft IOLs and inserting them into the eye. These include the use of forceps with relatively long blades which can engage an IOL and hold it in a folded position while it is inserted into the eye as shown, for example, in U.S. patents 5,007,913; 5,100,410 and 5,178,622. The disadvantage of these forceps devices is that they are difficult to operate. As the forceps blades release the IOL, its positioning is not tightly controlled within the eye and movement of the forceps blades could cause the incision to be enlarged. In addition, any movement close to the inner surface of the cornea is undesirable because the forceps blades or lens could rub against the endothelial cells on the inner surface of the cornea, which are not regenerative, and cause permanent damage. Since the forceps are manually squeezed by the surgeon, there is also the possibility that too much pressure could damage various portions of the IOL.

Another type of insertion instrument which has been developed includes a chamber in which an IOL is inserted. The IOL is folded, rolled or otherwise deformed or compressed during the insertion process. The IOL is then pushed or expressed out of an

- 4 -

elongated tip by a plunger after the tip is inserted into the eye.

While this type of inserter has the advantage of an elongated tip, which does not have to be
5 opened or closed, projecting through a small incision for precise placement of an IOL, known designs have various moveable parts that are complicated to fabricate and assemble or the folding process requires several steps which prolong and
10 complicate the surgical procedure.

For example, a number of inserters have been developed where an envelope or paddle is moved to project from the distal tip of the inserter, which operates to fold the IOL as it is pulled back into
15 the inserter. The IOL is implanted when the paddle is afterward moved to project from the tip by a physician. See, for example, U.S. patents 4,836,201; 4,880,000; 4,934,363 and 5,098,439. Others have jaw-like portions that operate to fold
20 the IOL as they close or telescopic sections that move relative to each other to hold the lens after it has been folded. See, for example, U.S. patents 4,714,373; 4,747,404 and 4,834,094.

An inserter was also developed, as shown in
25 U.S. patent 4,919,130, where a cannula is designed to receive an IOL that is partially folded. A first plunger pushes the IOL through a rigid chamber of gradually diminishing diameter to fold it completely. A second plunger then pushes the IOL
30 out of the cannula and into the eye.

- 5 -

In another inserter, shown in U.S. patent 4,681,102, an IOL is placed in an open cartridge which has two tabs or wing-like sections that are hinged together. The IOL is folded as the sections are closed. The cartridge is then placed in an inserter where an insertion cone, with an opening coextensive with the opening in the cartridge, is either placed over or formed adjacent to the cartridge. A single plunger is used to push the folded lens through the insertion cone and into the eye.

Because of the moving parts in many of the folding devices discussed above, the IOL can easily be pinched or torn during the folding or insertion process. In addition, folding and loading require a certain amount of manual manipulation of the IOL, which takes time and complicates the procedure. In the device where a cannula is used, a first plunger is used to fold the lens, which must be removed and replaced by a second plunger for inserting the lens in the eye.

Thus, there is a perceived need for an apparatus and method for folding an IOL and positioning it for insertion in the eye, which are less complicated than known devices and methods and eliminate moving parts which can pinch and tear the IOL and unneeded steps in the folding process.

Summary of the Invention

An improved intraocular lens compression chamber and associated insertion instrument and

- 6 -

method have been developed which solve the problems discussed above.

The compression chamber has an elongated IOL loading area which has an opening at a proximal lens receiving end that leads to an elongated passageway. The opening is large enough to receive a deformable or compressible IOL held by the blades of a pair of forceps, where the IOL is substantially in its open position. The passageway gradually decreases in size for a predetermined distance so that when the lens is pushed through the passageway, the lens is deformed or compressed by the walls defining the passageway. The lens is engaged and pushed through the passageway by the pair of forceps which can easily be withdrawn after the IOL has been deformed or compressed and placed in a staging area in the chamber.

In a preferred embodiment, the loading area has an open elongated slot in the sidewall so that the forceps blades can easily be withdrawn after the lens is fully inserted in the staging area. The passageway preferably has a circular cross section at the proximal lens receiving end, which gradually tapers to join an elliptical passageway at the entrance to the staging area, where the IOL is completely deformed or compressed after it is pushed into the staging area.

In an alternative embodiment a pair of elongated alignment grooves are located on the top interior portion of the staging area passageway for guiding movement of the IOL. The grooves gradually

- 7 -

decrease in depth as the passageway cross-section tapers from a grooved ellipse to an ellipse without grooves.

5 In a further alternative embodiment, the inner surface of the proximal lens receiving end can be crimped or threaded for preventing the IOL from slipping out of the loading area.

10 The loading area may be somewhat flexible at the proximal end for making the deforming or compressing step easier, with the staging area being relatively rigid for maintaining the IOL in place in a deformed or compressed configuration as it is advanced. The compression chamber also includes a distal tip that is long enough to insert through a
15 relatively small incision in the eye and is relatively flexible for enabling the IOL to be expressed into the patient's eye.

20 The compression chamber is designed to be mounted in a housing which has a slot for receiving a tab that projects from the outer surface of the compression chamber. The tab enables the chamber to be conveniently held when the IOL is deformed or compressed and to hold the chamber in the housing. The distal end of the loading chamber projects from
25 the housing when the compression chamber is mounted in the housing. A plunger is associated with the inserter, which is movable through the passageway in the compression chamber, from the proximal end of the loading area, into engagement with the deformed
30 or compressed lens in the staging area, to push the folded IOL through the distal tip and into the eye.

- 8 -

A compression chamber is therefore provided which has no moving parts so that an IOL can be inserted through a gradually-decreasing-diameter loading area with a pair of long-bladed forceps and pushed into a staging area. The walls of the loading area cause the IOL to be deformed and/or compressed. When the IOL is in the staging area it is in a position where it can easily be inserted into the eye after the compression chamber is mounted in a housing which has a single plunger for forcing the IOL out of the compression chamber.

Brief Description of the Drawings

A better understanding of the invention can be obtained when the detailed description of exemplary embodiments set forth below is considered in conjunction with the appended drawings, in which:

FIGURE 1 is a diagrammatic view of a foldable intraocular lens being inserted into an eye from a compression chamber made in accordance with the invention;

FIGURE 2 is a perspective view of the compression chamber of Fig. 1, showing in particular a foldable IOL held by a pair of forceps ready to be inserted in the proximal end of the loading area of the compression chamber;

FIGURE 3 is a perspective view of the compression chamber of Fig. 2, with the lens partially inserted in the loading area;

FIGURE 4 is an end view looking along site line 4-4 of Fig. 3;

- 9 -

FIGURE 5 is a perspective view of the compression chamber, partially broken away, with an IOL fully inserted in the staging area of the compression chamber;

5 FIGURE 6 is an end view looking along the site line 6-6 of Fig. 5;

FIGURE 7 is a sectional view of the compression chamber of Figs. 2-6 mounted in an inserter as shown in Fig. 1, with a deformed and/or compressed IOL
10 ready to be expressed into an eye;

FIGURE 8 is a top plan view of the insertion of Fig. 7 looking along the site line 8-8 of Fig. 7;

FIGURE 9 is a sectional view of the inserter shown in Fig. 7, with a plunger expressing the
15 deformed or compressed IOL out of the distal end of the compression chamber;

FIGURE 10 is a sectional view of the inserter of Fig. 9 looking along the site line 11-11 of Fig. 9;

20 FIGURE 11 is a detailed sectional view of the proximal end of the inserter looking along the site line 12-12 of Fig. 9.

FIGURE 12 is a fragmented plan view of a first alternative design of the distal tip of the
25 compression chamber;

FIGURE 13 is a fragmented plan view of a second alternative design of the distal tip;

FIGURES 13a-c are fragmented plan views of further alternative designs of the distal tip;

- 10 -

FIGURE 14 is a perspective view of an alternate compression chamber with a pair of alignment grooves for guiding movement of the IOL;

FIGURE 14a is a perspective partial view of the
5 compression chamber of Fig. 14;

FIGURE 15 is an end view looking along site line 15-15 of Fig. 14;

FIGURE 16 is a side plan view of the compression chamber of Fig. 14;

10 FIGURE 17 is a cross sectional view looking along site line 17-17 of Fig. 16;

FIGURE 18 is a cross sectional view looking along site line 18-18 of Fig. 16

15 FIGURE 19 is a cross sectional view looking along site line 19-19 of Fig. 16;

FIGURE 20 is a cross sectional view looking along site line 20-20 of Fig. 16;

20 FIGURE 21 is perspective view of the alternate compression chamber showing the passageway of the staging area in phantom;

FIGURE 22 is a fragmented perspective view of a alternate design of the proximal end of the compression chamber; and

25 FIGURE 23 is a fragmented perspective view of an other alternate design of the proximal end of the compression chamber.

Detailed Description of Exemplary Embodiments

The subject invention is directed to a compression chamber 10, shown in detail in Figs. 2-
30 6, which is useful for rolling, folding or otherwise

- 11 -

deforming or compressing an IOL 12 formed of a soft material such as, for example, silicone or a hydrogel, so the IOL can be inserted into the eye of a patient. As shown in Fig. 1, after the IOL 12 is
5 deformed or compressed and positioned in a staging area in the compression chamber 10, as described in greater detail below, the compression chamber 10 is mounted in an insertion device, generally designated by reference numeral 14, for inserting the IOL 12
10 into a patient's eye 16 after an elongated distal tip 18 is inserted through an incision formed in the eye.

The compression chamber 10, shown in detail in Figs. 2-6, includes a loading area 20 which is
15 formed at a proximal end 22 of the compression chamber 10. The loading area 20 has an internal passageway that is generally circular in cross section and is sized to be about .160" in diameter at the proximal end 22, which is approximately the
20 width of a leading edge 24 of the IOL 12 to allow for relatively easy insertion of the IOL 12 into the loading area 20. The opening may be elliptical, ovoid, circular, hexagonal or other appropriate shape.

25 As shown in Fig. 2, an IOL which has an optic portion 26 and a surrounding support or haptic portion 28, formed of a single piece of material, is shown ready to be inserted into the compression chamber 10. It should be understood, however, that
30 IOLs formed of more than one piece of material such as, for example, an optic which has a pair of loops

- 12 -

or haptics connected at the outer periphery of the optic (not shown) could also be used with the compression chamber 10.

The compression chamber 10 is preferably formed
5 of a polypropylene polymer such as, for example,
that sold by Huntsman Chemical Corp., No. 5B25Z.
This material can easily be injection molded into
the shape as shown and described, which will have a
relatively smooth inner surface and can be
10 sterilized.

Insertion of the IOL 12 into the compression
chamber 10 is preferably done with a pair of forceps
30 which can either have angled forceps blades 32 as
shown in Figs. 2 and 3, or be of the straight-bladed
15 variety (not shown). The blades 32 must be long
enough so that they can grip the IOL 12 as shown and
push it through the loading area 20 (see Fig. 3) and
into a staging area 34 shown in Fig. 5.

Before the IOL 12 is inserted into the
20 compression chamber 20, the loading area is
lubricated by depositing an amount of a solution
directly into the opening. This solution may be a
known viscoelastic solution which is also typically
injected into the eye during IOL surgery, which
25 operates to protect cells and tissue on the inner
surface of the cornea as well as maintain the shape
of the eye during surgery. The solution may also be
a balanced salt solution which is commonly used
during eye surgery.

30 It has been found that for best results, the
solution should be generously applied to the

- 13 -

interior of the compression chamber, but not to the outer surface of the IOL 12. This allows the forceps blades 32 to grip the IOL 12 firmly without slipping.

5 As shown best in the cross-sectional views in Figs. 7 and 9, the loading area 20 is defined by a passageway having an inner surface 21 which is cylindrical in cross section (or other appropriate shape) and gradually decreases in diameter from
10 about .160" to about .101". The wall of the loading area 20 is thinner at the proximal end 22 and gradually increases in width as the passageway approaches the staging area 34. The loading area 20 is formed with a slot 36 so that once the IOL is
15 inserted in the staging area 34, the forceps blades 32 can easily be withdrawn. As shown in Figs. 4 and 6, a groove 38 may be formed on the passageway inner surface 21 along the bottom of the wall that defines the loading area 20, opposite the slot 36, which
20 facilitates withdrawal of the lower forceps blade 32.

 Inclusion of the slot 36 and the relatively thin walls defining the loading area 20 provide flexibility to the walls so that as the IOL 12 is
25 pushed from the position shown in Fig. 2 to the position shown in Fig. 3, and into the deformed or compressed position in the staging area 34 as shown in Fig. 5, the shaping of the IOL 12 is more easily achieved. As shown in Figs. 2 and 4, the IOL 12 is
30 inserted directly into the proximal end 22 of the loading area 20. As the IOL 12 is pushed toward the

- 14 -

staging area 34, the walls which define the loading area operate to cause the sides of the IOL 12 to curl upwardly. As the IOL 12 is pushed toward the staging area 34, the diminishing-diameter surface of the loading area 20 causes the IOL 12 to deform and compress from the position shown in Fig. 4 to the position shown in Fig. 6.

A pair of ridges 40 may be formed on the inner surface 21 of the walls which define the loading area 20 for guiding the outer edges of the haptic portion 28 of the IOL 12. As shown in Fig. 4, when the IOL 12 is initially inserted it is aligned beneath the ridges 40. For example, as best illustrated in Fig. 5, the ridges 40 can begin at approximately the center of the wall of the loading area 20 at the distal end 22, and move upwardly along the surface of the wall which defines the loading area 20 or alternatively the ridges 40 can begin at any position along the side of the loading area wall. The ridges 40 guide the edges of the haptics 28 into their curled position until they reach the staging area 34 shown in Fig. 6.

The staging area 34 is formed with a passageway that operates as a continuation of the passageway in the loading area 20. The staging area passageway also gradually diminishes in size along its length, but is preferably formed with an elliptical cross-section, instead of one which is circular. The passageway in the staging area 34 has a cross-sectional dimension adjacent to the loading area of generally .101" in the long dimension and generally

- 15 -

.095" in the short dimension, which decreases in size in the short dimension until the passageway measures generally .101"/.086". The wall of the compression chamber 10 which defines the staging area 34 is relatively thick so that as the IOL 12 is pushed into the staging area 34, the wall will not flex but will maintain the IOL in the deformed or compressed position shown in Fig. 6.

In an alternate embodiment, a compression chamber 10A has a staging area 34a formed with a passageway having a top and bottom passageway wall 33a, 33b as shown in Figs. 14 and 15. The staging area passageway also gradually diminishes in size along its length and is preferably formed with an elliptical cross-section with two intersecting semi-circles or grooves 35, as illustrated in Figs. 14a and 21. The staging area passageway has a cross-sectional dimension adjacent to the loading area of .101" in both the vertical and horizontal axis, which decreases in size in along the vertical axis until the passageway measures about .101" in the horizontal axis and about .086" in the vertical axis. The pair of elongated grooves 35 are formed in the top passageway wall 33a with the grooves 35 beginning at the entrance to the staging area 34a. As the staging area passageway gradually diminishes in size along its length, the grooves 35 decrease in radius to form a passageway having an elliptical cross-section as shown in Figs. 16-21. In the preferred embodiment, the grooves begin with a radius of about .017" and decrease to a radius of

- 16 -

zero (0) forming the elliptical cross-section illustrated in Fig. 20.

5 The grooves 35 align and retain the IOL 12 in its curled position as the IOL 12 is inserted into the loading area 20 and guided into the staging area 34a as shown in Fig. 15. The grooves 35 and the diminishing passageway of the staging area 34a cause the IOL 12 to continue curling or folding as it is guided through the staging area 34a and out the
10 distal end 18 as shown in Fig. 21.

In order to maintain the IOL 12 in the loading area 20, the compression chamber 10, 10A can include threads 80 on the passageway inner surface 21. The threads can be placed circumferentially on the
15 passageway inner surface 21 at the intersection of the loading area 20 and the staging area 34, 34a, as shown in Fig. 14a or at the proximal end of the chamber 10, 10A, as shown in Fig. 22.

Alternatively, the proximal end 22 of the chamber
20 10, 10A can be slightly compressed 82 and crimped 84, as shown in Fig. 23, in order to hold the IOL 12 in the loading area 20. For example, the dimension of the compressed proximal end can be about .220" along the horizontal axis and about .12 along the
25 vertical axis.

After the IOL 12 is loaded as described and shown, the compression chamber 10 or 10A, depending on the embodiment, is mounted in an insertion instrument 14 of a known type. This instrument may
30 be formed of a sterilizable material such as stainless steel or titanium and includes a holding

- 17 -

section 42 which has a slot 44 in which the compression chamber 10 is initially inserted.

A tab or handle 48 is formed integral with the compression chamber 10, 10A which fits snugly in a slot 46 for holding the compression chamber 10, 10A in place in the holding section 42. The tab 48 also makes the compression chamber 10, 10A easy to hold during insertion of the IOL 12. In a preferred embodiment, the tab 48 is positioned over the staging area 34 portion of the chamber 10, 10A.

The distal tip 18 of the compression chamber 10, 10A projects through an opening 50 formed on the distal end of the inserter 14 so that the distal tip 18 can be inserted through an incision formed in the outer surface of the eye 16 (see Fig. 1).

The distal tip 18 has a relatively thin wall and a passageway that is slightly elliptical in cross section, but which decreases in size along both the long and short dimensions of the ellipse. For example, the passageway in the distal tip 18 is generally .101"/.086" adjacent to the staging area 34, and decreases to generally .097"/.082" until it communicates with a truncated tip 52 which diminishes in size to its distal end to generally .085"/.070" or smaller. As shown in the sectional views of Figs. 7 and 9, the distal tip and truncated end have a relatively thin wall to allow some flexibility for enabling the IOL 12 to be expressed more easily as described in greater detail below. With the dimensions of the distal tip 18 and

- 18 -

truncated end 52, an incision of about 2.8 mm or slightly more is needed in the eye 16.

The IOL 12 is moved from the staging area 34, 34A through the distal tip 18 and the truncated end 52 by means of a plunger 54 movable within the inserter 14. The plunger 54 may have a threaded proximal end 56 which engages cooperating threads 58 formed internally in the inserter 14, so that when a knob 60 is rotated a plunger tip 62, formed in a known way into a cup-shape, is moved into engagement with the IOL 12. Further rotation of the knob 60 causes the plunger tip 62 to move forward to force the IOL 12 through the staging area 34 and distal tip 18 so that the IOL 12 is expressed out of the truncated end 52 as shown in Figs. 1 and 9.

As shown in particular in Fig. 10, a plug 64 is mounted in the inserter housing 14 to engage a flattened side 66 of the plunger 54 to prevent the plunger from rotating as it is moved forward. As shown in Fig. 11, the plunger 54 includes a flattened end 68, located in the knob 60, so that the knob 60 can rotate relative to the plunger 54 to move the plunger 54 forward for expressing the IOL as described. An end piece 70 is mounted in the knob 60 for bearing against the flattened head 68 and pushing the plunger 54 forward as the knob 60 is rotated.

The truncated tip 52 may be formed with a flat distal end 53 as shown in Figs. 7-9 or, alternatively, in other shapes which will assist in expressing an IOL in various ways. For example, as

- 19 -

shown in Fig. 12 the tip 52 may be beveled at an angle A of about 35°-50°, preferably about 45°, for allowing the IOL 12 to gradually unfold as it is expressed. The tip 52 may alternatively be formed
5 with one or more slits 70 along the length of the truncated portion 52 for allowing the haptic portions to expand gradually prior to the optic being expressed from the distal end.

By way of illustration, a single slit may be
10 used so that the IOL can move toward the side of the slit as the IOL is expressed. A pair of the slits 70, for a single-piece IOL 12 or for multi-piece IOLs (not shown), are preferable so that the IOL is expressed axially from the truncated tip 52.

15 Obviously, other designs may be used for other types of expressing characteristics such as, for example, slots or other irregularly shaped openings. For example, the irregularly shaped openings can include a generally clover shaped opening 55a having
20 a cross-sectional dimension of about 0.063" as shown in Fig. 13a, a generally bag shaped opening 55b having a cross-sectional dimension along its short axis of about 0.047" to 0.051" as shown in Fig. 13b, or a generally duck-mouth shaped opening 55c having
25 a cross-sectional dimension along its short axis of about 0.035" to 0.043" as shown in Fig. 13c. The thin wall of the distal tip 18 and the truncated end 52 allow for flexing of the openings 55a, 55b and 55c which will assist in expressing an IOL 12 in
30 various ways depending upon the shape of the opening.

- 20 -

Thus, a compression chamber for deforming and/or compressing an IOL has been described which is advantageous over all known compression chambers since an IOL is deformed or compressed exclusively through a single step of inserting an IOL into a staging area by means of a pair of forceps. There are no moving parts to complicate fabrication or to pinch the IOL during the folding process. The compression chamber is easily mounted in an insertion device so that the IOL can be pushed through the chamber and expressed into a proper location in the eye of a patient. This pushing is done through the use of a single plunger because the IOL has already been mounted in a staging area adjacent to the portion that is inserted into the eye. The compression chamber is designed to be flexible and rigid in respective strategic locations in order to enhance the ability of an operator to insert an IOL and deform or compress it with a pair of forceps in a single step, and then to express the IOL into a patient's eye.

It will become apparent to one of ordinary skill in the art that modifications and improvements can be made to the invention without departing from the spirit and scope of the invention, and it is contemplated that all such modifications and improvements will fall within the scope of the invention as defined in the appended claims.

- 21 -

CLAIMS

What is claimed is:

- 1 1. An apparatus in which a deformable or
2 compressible intraocular lens can be received and
3 staged for insertion into a patient's eye,
4 comprising:
 - 5 (a) an elongated compression chamber
6 having proximal and distal ends and a longitudinal
7 passageway extending between the ends, said
8 passageway having an inner surface;
 - 9 (b) the portion of the passageway
10 adjacent to the proximal end forming a loading area
11 in which the passageway gradually decreases in size
12 for causing an intraocular lens to be deformed or
13 compressed as the lens is moved along the
14 passageway;
 - 15 (c) a staging area having a top and
16 bottom passageway wall, said staging area
17 communicating with the loading area, said passageway
18 wall in the staging area including alignment means
19 for maintaining the alignment of the lens as it is
20 moved along the passageway, the passageway changing
21 in shape in the direction the lens is moved for
22 compressing and folding the lens as it is moved
23 along the passageway, a portion of the passageway
24 being sized to retain the intraocular lens in the
25 deformed or compressed condition;
 - 26 (d) the portion of the passageway
27 defining the loading area comprising a surface which
28 includes means for permitting withdrawal of a
29 holding means used for pushing the intraocular lens

- 22 -

30 through the loading area and into the staging area
31 for deforming or compressing the lens; and
32 (e) the passageway defining the loading
33 area further including maintaining means for
34 maintaining the lens in the loading area.

1 2. The apparatus of claim 1, wherein the
2 compression chamber further includes an elongated
3 distal tip with an extension of the passageway in
4 the staging area, the tip having an outer end
5 adapted for insertion through a small incision in a
6 patient's eye so that a lens in the staging area can
7 be moved through the passageway in the tip for
8 insertion in a patient's eye.

1 3. The apparatus of claim 2, wherein the
2 loading area, staging area and distal tip are formed
3 as an integral unit.

1 4. The apparatus of claim 1, wherein the
2 loading area is generally circular in cross-section
3 along its length.

1 5. The apparatus of claim 4, wherein the
2 passageway in the loading area has a diameter at the
3 proximal end of about .160" and decreases to a
4 diameter of about .101".

1 6. The apparatus of claim 1, wherein the
2 maintaining means for maintaining the lens in the

- 23 -

3 loading area includes threads positioned at the
4 proximal end of the chamber.

1 7. The apparatus of claim 1, wherein the
2 maintaining means includes threads on the inner
3 surface of a portion of the passageway at the
4 intersection between the loading area and the
5 staging area.

1 8. The apparatus of claim 1, wherein the
2 maintaining means further includes compressing and
3 crimping of the proximal chamber end.

1 9. The apparatus of claim 1, wherein the
2 staging area passageway decreases in size towards
3 the distal end of the compression chamber.

1 10. The apparatus of claim 1, wherein the
2 alignment means in the staging area includes an
3 ellipse with two intersecting semi-circles forming a
4 pair of elongated grooves.

1 11. The apparatus of claim 10, wherein the
2 grooves are formed in the top wall of the staging
3 area passageway.

1 12. The apparatus of claim 10, wherein the
2 grooves have a radius that decreases from about
3 .017" to a radius of zero (0).

- 24 -

1 13. The apparatus of claim 10, wherein the
2 elliptical passageway in the staging area has a
3 dimension of about .101" along both a vertical and
4 horizontal axis adjacent to the loading area, which
5 decreases in size to a dimension of about .101" in
6 the horizontal axis and a dimension of about .086"
7 in the vertical axis at its other end.

1 14. The apparatus of claim 1, wherein the
2 means for permitting convenient withdrawal of the
3 holding means includes a slot formed in the surface
4 defining the loading area.

1 15. The apparatus of claim 2, wherein the
2 distal tip has a passageway that is elliptical in
3 cross section, along its length.

1 16. The apparatus of claim 15, wherein the
2 elliptical passageway in the distal end is about
3 .101" x .086" adjacent to the staging area and
4 decreases in size to about .085" x .070" at its
5 outer end.

1 17. The apparatus of claim 1, wherein the
2 chamber further includes tab means projecting
3 outwardly from the staging area for allowing the
4 chamber to more conveniently be gripped by a user.

1 18. The apparatus of claim 1, further
2 including a housing for holding the compression
3 chamber, the housing having a receiving portion for

- 25 -

4 receiving the compression chamber and a slot over at
5 least a portion of the receiving portion for
6 receiving the tab means so that the compression
7 chamber can be held in place after the compression
8 chamber is moved in the receiving portion.

1 19. The apparatus of claim 18, wherein the
2 housing includes an end opening aligned with the
3 distal end of the compression chamber, and plunger
4 means for pushing a deformed or compressed lens in
5 the staging area out of the distal end of the
6 compression chamber.

1 20. A method for deforming or compressing an
2 intraocular lens and staging it for insertion into a
3 patient's eye, comprising the steps of:

4 (a) holding the lens with a grasping
5 means which engages the lens on opposite sides when
6 the lens is in an undeformed or uncompressed
7 condition;

8 (b) inserting the lens into the proximal
9 end of a loading area portion of a compression
10 chamber, the loading area having a longitudinal
11 passageway with a cross sectional dimension at the
12 proximal end about the width of the lens, and
13 gradually decreasing in size extending from the
14 proximal end;

15 (c) deforming or compressing the lens by
16 pushing it through the passageway while holding the
17 lens with the grasping means, the surface defining

- 26 -

18 the passageway causing the lens to gradually deform
19 or compress as it is pushed through the passageway;
20 (d) pushing the deformed or compressed
21 lens into a staging area with alignment means for
22 maintaining the alignment of the lens as it is moved
23 along the passageway, the passageway changing in
24 shape in the direction the lens is moved for
25 compressing and folding the lens as it is moved
26 along the passageway in a deformed or compressed
27 condition while holding the lens with the grasping
28 means;
29 (e) withdrawing the grasping means after
30 the lens is in a deformed or compressed condition in
31 the staging area.

1 21. The method of claim 20, wherein the step
2 of holding the lens includes grasping the lens with
3 a pair of forceps with blades long enough to reach
4 through the loading area and into the staging area.

1 22. The method of claim 21, wherein the step
2 of holding includes grasping the lens with a pair of
3 forceps with straight blades.

1 23. The method of claim 21, wherein the step
2 of holding includes grasping the lens with a pair of
3 forceps with blades formed with an angle between the
4 portion that grasps the lens and a portion held by a
5 user.

- 27 -

1 24. The method of claim 20, and further
2 including the step of lubricating the loading area
3 with an ophthalmic viscoelastic solution before step
4 (b) of inserting the lens.

1 25. The method of claim 20, wherein the steps
2 of inserting and withdrawing the grasping means
3 include at least one of the forceps blades traveling
4 through an opening in the surface defining the
5 loading area, said opening being along at least a
6 portion of the length of the loading area.

1 26. The method of claim 20, wherein the steps
2 of inserting and withdrawing include a forceps blade
3 moving through a slot in the surface defining the
4 loading area.

1 27. The method of claim 20, wherein the steps
2 of inserting and withdrawing include a forceps blade
3 moving through a groove in the surface defining the
4 loading area.

1 28. The method of claim 20, wherein the step
2 of inserting the lens includes pushing the lens
3 through a loading chamber with a wall sized and
4 shaped to flex as the lens moves through the
5 passageway.

1 29. The method of claim 20, wherein the step
2 of deforming or compressing includes pushing the

- 28 -

3 lens through a loading area with a slot in the wall
4 extending from the proximal end.

1 30. The method of claim 20, wherein the step
2 of pushing the lens into a staging area includes
3 providing a staging area that does not flex as the
4 lens moves through it.

1 31. The method of claim 20, and further
2 including the steps of :

3 (f) mounting the compression chamber in a
4 housing after the grasping means has been withdrawn;
5 and

6 (g) pushing the folded lens out of the
7 staging area and through a distal tip for inserting
8 the lens in the eye of a patient.

1 32. The method of claim 31, wherein the step
2 of pushing the folded lens includes moving a plunger
3 associated with the housing, which engages the
4 proximal end of the lens.

1 33. An apparatus in which a deformable or
2 compressible intraocular lens can be received and
3 staged for insertion into a patient's eye,
4 comprising:

5 (a) an elongated compression chamber
6 having proximal and distal ends and a longitudinal
7 passageway extending between the ends;

8 (b) the portion of the passageway
9 adjacent to the proximal end forming a loading area

- 29 -

10 in which the passageway gradually decreases in size
11 for causing an intraocular lens to be deformed or
12 compressed as the lens is moved along the
13 passageway;

14 (c) a staging area communicating with the
15 loading area where a portion of the passageway is
16 sized to retain the intraocular lens in a deformed
17 or compressed condition;

18 (d) the portion of the passageway
19 defining the loading area comprising a surface which
20 includes means for permitting withdrawal of a
21 holding means used for pushing the intraocular lens
22 through the loading area and into the staging area
23 for deforming or compressing the lens.

1 34. The apparatus of claim 33, wherein the
2 compression chamber further includes an elongated
3 distal tip with an extension of the passageway in
4 the staging area, the tip having an outer end
5 adapted for insertion through a small incision in a
6 patient's eye so that a lens in the staging area can
7 be moved through the passageway in the tip for
8 insertion in a patient's eye.

1 35. The apparatus of claim 34, wherein the
2 loading area, staging area and distal tip are formed
3 as an integral unit.

1 36. The apparatus of claim 35, wherein the
2 integral unit is formed of an injection-molded,
3 sterilizable polymer.

- 30 -

1 37. The apparatus of claim 33, wherein the
2 loading area is circular in cross-section along its
3 length.

1 38. The apparatus of claim 37, wherein the
2 passageway in the loading area has a diameter at the
3 proximal end of about .160" and decreases to a
4 diameter of about .101".

1 39. The apparatus of claim 33, wherein the
2 means for permitting convenient withdrawal of the
3 holding means includes a slot formed in the surface
4 defining the loading area.

1 40. The apparatus of claim 33, wherein the
2 means for permitting easy withdrawal of the holding
3 means includes a groove formed in the surface
4 defining the loading area.

1 41. The apparatus of claim 33, wherein the
2 surface defining the loading area includes a wall
3 that is sized to allow at least the proximal end of
4 the loading area to flex as an intraocular lens is
5 inserted.

1 42. The apparatus of claim 33, wherein the
2 surface defining the loading area includes a pair of
3 ridges projecting into the loading area from
4 opposite sides, for engaging opposite edges of the
5 lens for guiding them to a deformed or compressed
6 position in the staging area.

- 31 -

1 43. The apparatus of claim 33, wherein the
2 portion of the passageway in the staging area is
3 elliptical in cross section, along its length.

1 44. The apparatus of claim 43, wherein the
2 elliptical passageway in the staging area is about
3 .101" in the long dimension to about .095" in the
4 short dimension adjacent to the loading area, which
5 decreases in size to .101" x .086" at its other end.

1 45. The apparatus of claim 33, wherein the
2 staging area includes a wall that is sized to
3 prevent flexing of the wall as the lens is moved
4 into and through the staging area.

1 46. The apparatus of claim 34, wherein the
2 distal tip has a passageway that is elliptical in
3 cross section, along its length.

1 47. The apparatus of claim 46, wherein the
2 elliptical passageway in the distal tip is about
3 .101" x .086" adjacent to the staging area and
4 decreases in size to about .085" x .070" at its
5 outer end.

1 48. The apparatus of claim 34, wherein the
2 distal tip includes a wall that is sized to be
3 flexible as the lens moves through the passageway.

- 32 -

1 49. The apparatus of claim 34, wherein the
2 outer end of the distal tip is beveled at an angle
3 relative to the passageway.

1 50. The apparatus of claim 34, wherein the
2 outer end of the distal tip has at least one
3 longitudinal slit extending from the outer end and
4 communicating with the passageway.

1 51. The apparatus of claim 50, wherein the
2 distal tip has a pair of slits on opposite sides of
3 the passageway.

1 52. The apparatus of claim 2 or 34, wherein
2 the outer end of the distal tip has an irregularly
3 shaped opening generally in the form of a clover
4 shape allowing for ease in expressing the lens.

1 53. The apparatus of claim 2 or 34, wherein
2 the outer end of the distal tip has an irregularly
3 shaped opening generally in the form of a bag shape
4 allowing for ease in expressing the lens.

1 54. The apparatus of claim 2 or 34, wherein
2 the outer end of the distal tip has an irregularly
3 shaped opening generally in form of a duck-mouth
4 shape allowing for ease in expressing the lens.

1 55. The apparatus of claim 33 and further
2 including tab means projecting outwardly from the

- 33 -

3 loading area for allowing the chamber to more
4 conveniently be gripped by a user.

1 56. The apparatus of claim 33, and further
2 including a housing for holding the compression
3 chamber, the housing having a receiving portion for
4 receiving the compression chamber and a slot over at
5 least a portion of the receiving portion for
6 receiving the tab means so that the compression
7 chamber can be held in place after the compression
8 chamber is moved in the receiving portion.

1 57. The apparatus of claim 56, wherein the
2 housing includes an end opening aligned with the
3 distal end of the compression chamber, and plunger
4 means for pushing a deformed or compressed lens in
5 the staging area out of the distal end of the
6 compression chamber.

1 58. An apparatus in which a deformable or
2 compressible intraocular lens can be received and
3 staged for insertion into a patient's eye,
4 comprising:

5 (a) an elongated compression chamber
6 having proximal and distal ends and a longitudinal
7 passageway extending between the ends;

8 (b) the portion of the passageway
9 adjacent to the proximal end forming a loading area
10 in which the passageway gradually decreases in size
11 for causing an intraocular lens to be deformed or

- 34 -

12 compressed as the lens is moved along the
13 passageway;

14 (c) a staging area communicating with the
15 loading area where a portion of the passageway is
16 sized to retain the intraocular lens in a deformed
17 or compressed condition;

18 (d) the portion of the passageway
19 defining the loading area comprising a wall which
20 has at least a flexible portion at the proximal end
21 so the loading area can deform as an intraocular
22 lens is pushed through the loading area and into the
23 staging area.

1 59. The apparatus of claim 58, wherein the
2 wall is relatively thin at least at the proximal end
3 of the loading area.

1 60. The apparatus of claim 59, wherein the
2 wall gradually increases in width from the proximal
3 end toward the staging area.

1 61. The apparatus of claim 58, wherein the
2 loading chamber includes a slot formed in the wall,
3 extending from the proximal end.

1 62. A method for deforming or compressing an
2 intraocular lens and staging it for insertion into a
3 patient's eye, comprising the steps of:

4 (a) holding the lens with a grasping
5 means which engages the lens on opposite sides when

- 35 -

6 the lens is in an undeformed or uncompressed
7 condition;

8 (b) inserting the lens into the proximal
9 end of a loading area portion of a compression
10 chamber, the loading area having a longitudinal
11 passageway with a cross sectional dimension at the
12 proximal end about the width of the lens, and
13 gradually decreasing in size extending from the
14 proximal end;

15 (c) deforming or compressing the lens by
16 pushing it through the passageway while holding the
17 lens with the grasping means, the surface defining
18 the passageway causing the lens to gradually deform
19 or compress as it is pushed through the passageway;

20 (d) pushing the deformed or compressed
21 lens into a staging area, while holding the lens
22 with the grasping means;

23 (e) withdrawing the grasping means after
24 the lens is in a deformed or compressed condition in
25 the staging area.

1 63. The method of claim 62, wherein the step
2 of holding the lens includes grasping the lens with
3 a pair of forceps with blades long enough to reach
4 through the loading area and into the staging area.

1 64. The method of claim 63, wherein the step
2 of holding includes grasping the lens with a pair of
3 forceps with straight blades.

- 36 -

1 65. The method of claim 63, wherein the step
2 of holding includes grasping the lens with a pair of
3 forceps with blades formed with an angle between the
4 portion that grasps the lens and a portion held by a
5 user.

1 66. The method of claim 62, and further
2 including the step of lubricating the loading area
3 with an ophthalmic viscoelastic solution before the
4 step of inserting the lens.

1 67. The method of claim 62, wherein the step
2 of inserting includes aligning the lens with a pair
3 of ridges projecting from the surface defining the
4 passageway in the loading area, the ridges guiding
5 the edges of the lens into a deformed condition as
6 the lens is pushed through the loading area.

1 68. The method of claim 63, wherein the steps
2 of inserting and withdrawing the grasping means
3 include at least one of the forcep blades traveling
4 through an opening in the surface defining the
5 loading area, along at least a portion of the length
6 of the loading area.

1 69. The method of claim 62, wherein the steps
2 of inserting and withdrawing include a forcep blade
3 moving through a slot in the surface defining the
4 loading area.

- 37 -

1 70. The method of claim 62, wherein the steps
2 of inserting and withdrawing include a forcep blade
3 moving through a groove in the surface defining the
4 loading area.

1 71. The method of claim 62, wherein the step
2 of deforming or compressing the lens includes
3 pushing the lens through a loading chamber with a
4 wall sized and shaped to flex as the lens moves
5 through the passageway.

1 72. The method of claim 62, wherein the step
2 of deforming or compressing includes pushing the
3 lens through a loading area with a slot in the wall
4 extending from the proximal end.

1 73. The method of claim 72, wherein the step
2 of pushing the lens into a staging area includes
3 providing a staging area that does not flex as the
4 lens moves through it.

1 74. The method of claim 62, and further
2 including the steps of :
3 (f) mounting the compression chamber in a
4 housing after the grasping means has been withdrawn;
5 and
6 (g) pushing the folded lens out of the
7 staging area and through a distal tip for inserting
8 the lens in the eye of a patient.

- 38 -

- 1 75. The method of claim 74, wherein the step
- 2 of pushing the folded lens includes moving a plunger
- 3 associated with the housing, which engages the
- 4 proximal end of the lens.

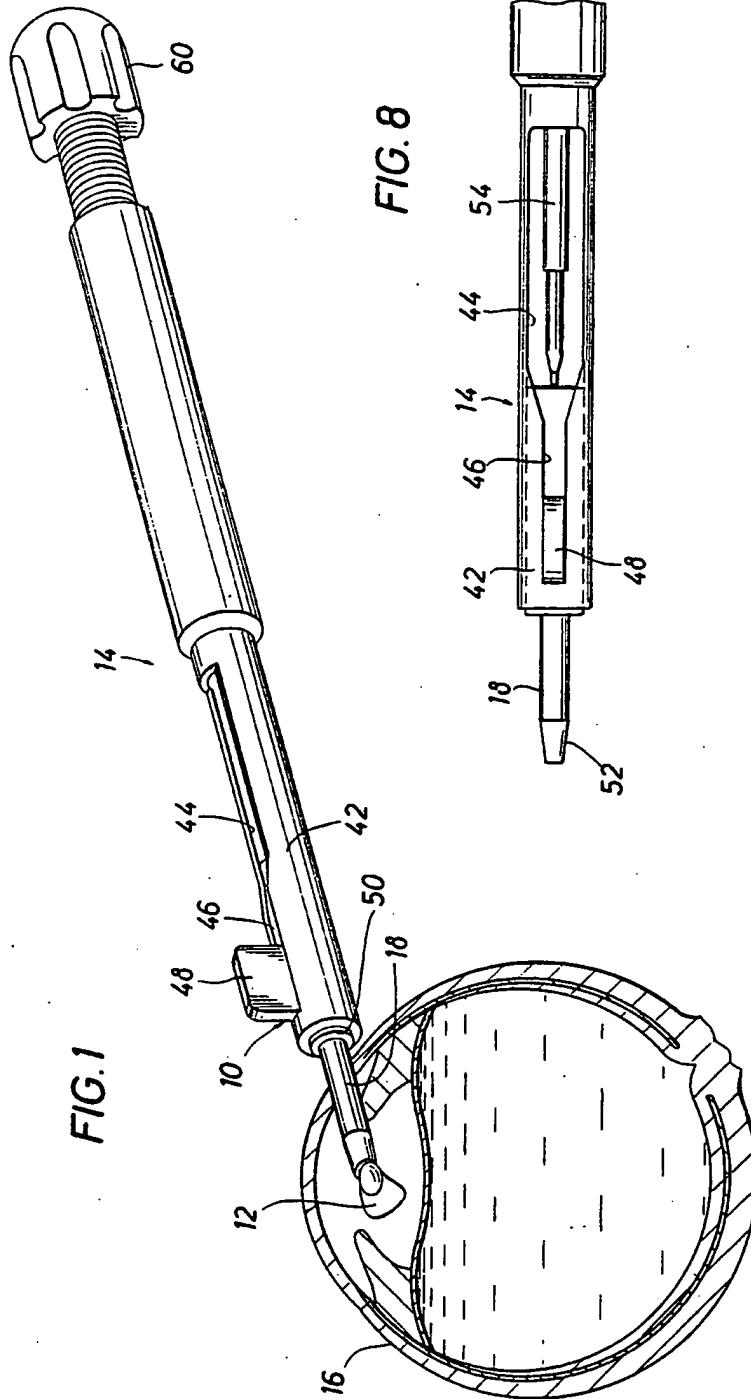


FIG. 1

FIG. 8

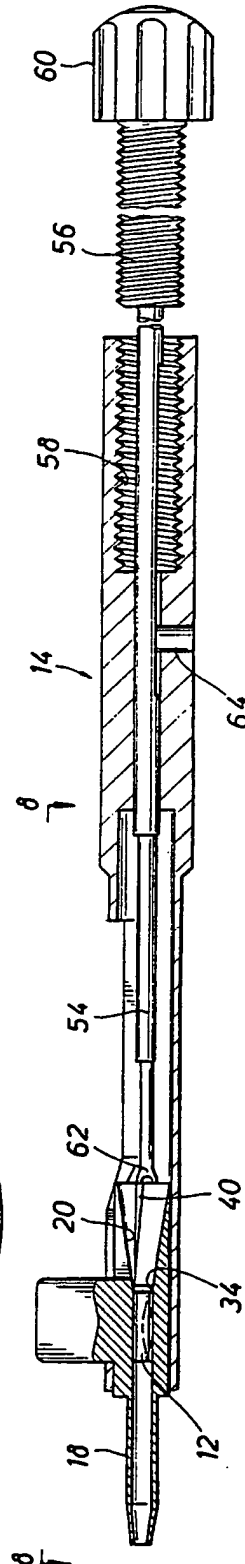
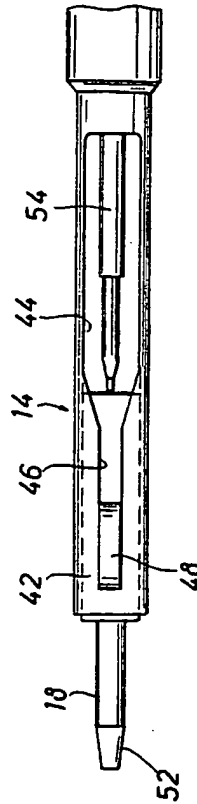


FIG. 7

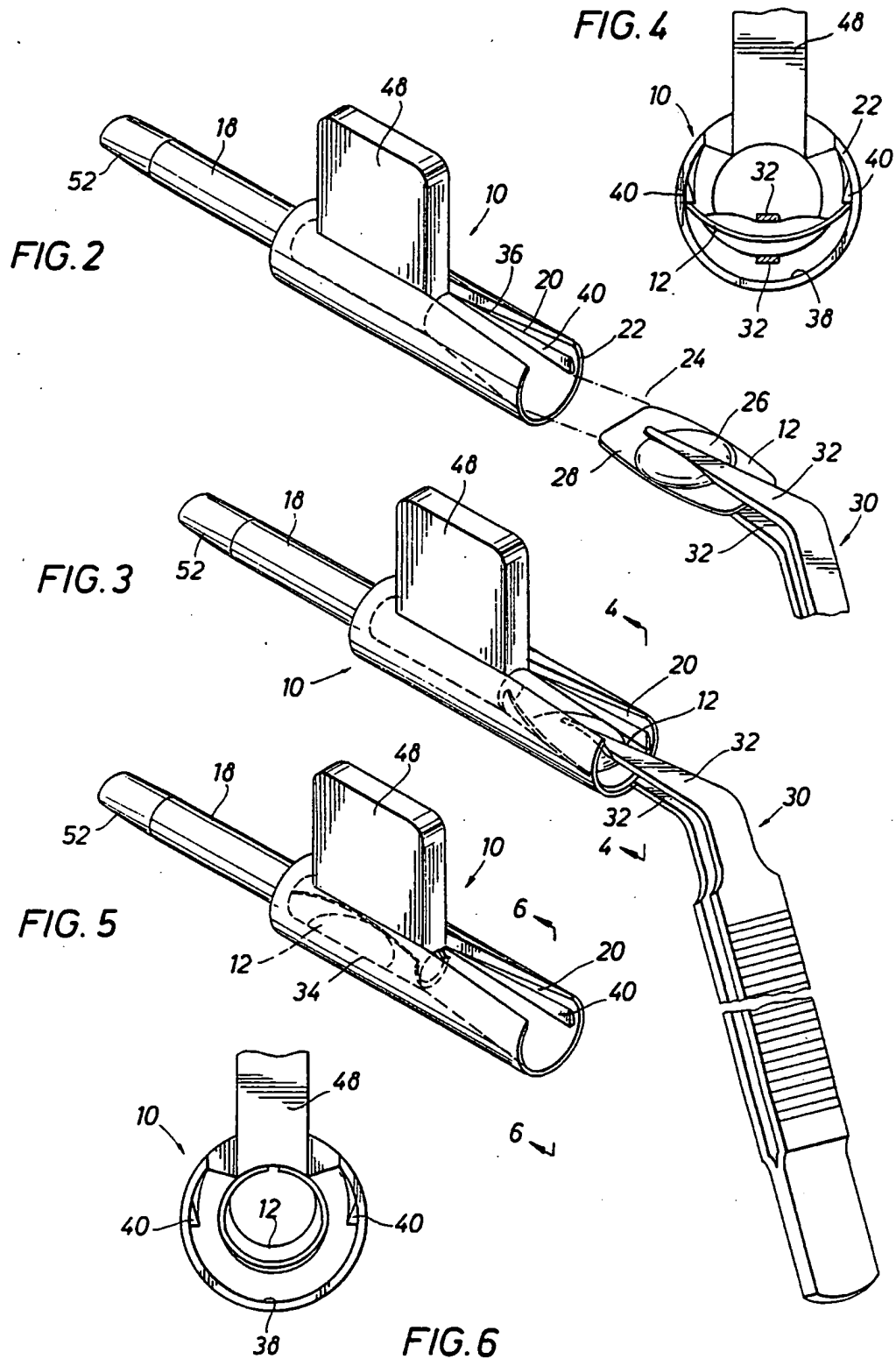


FIG. 9

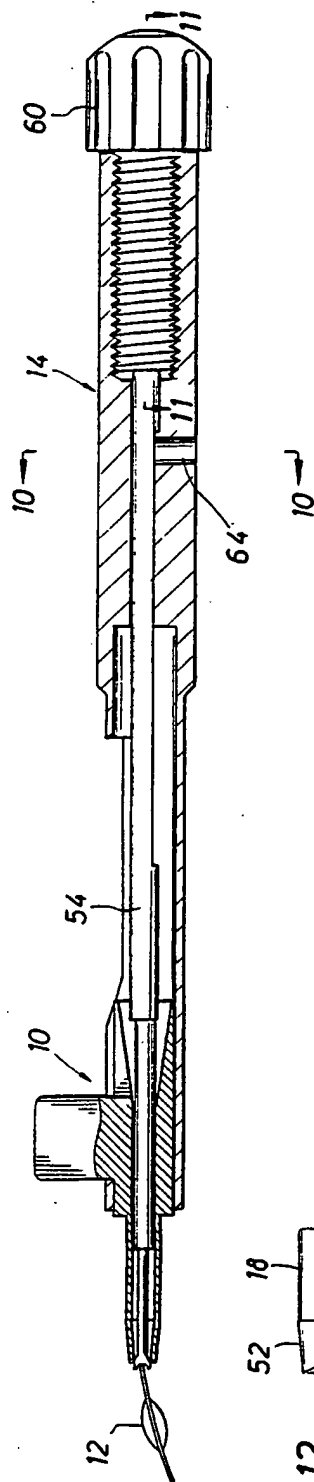


FIG. 12

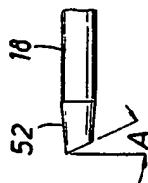


FIG. 13

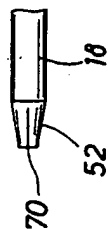


FIG. 10

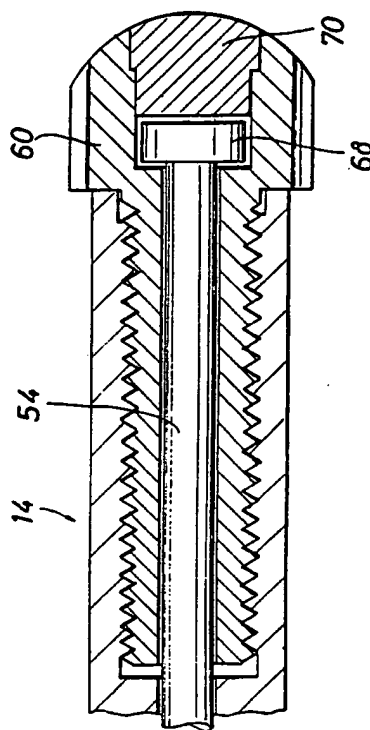
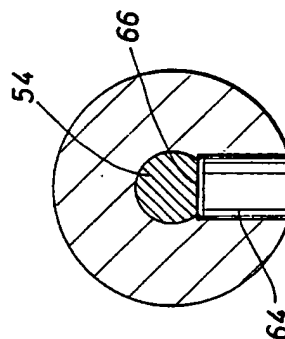
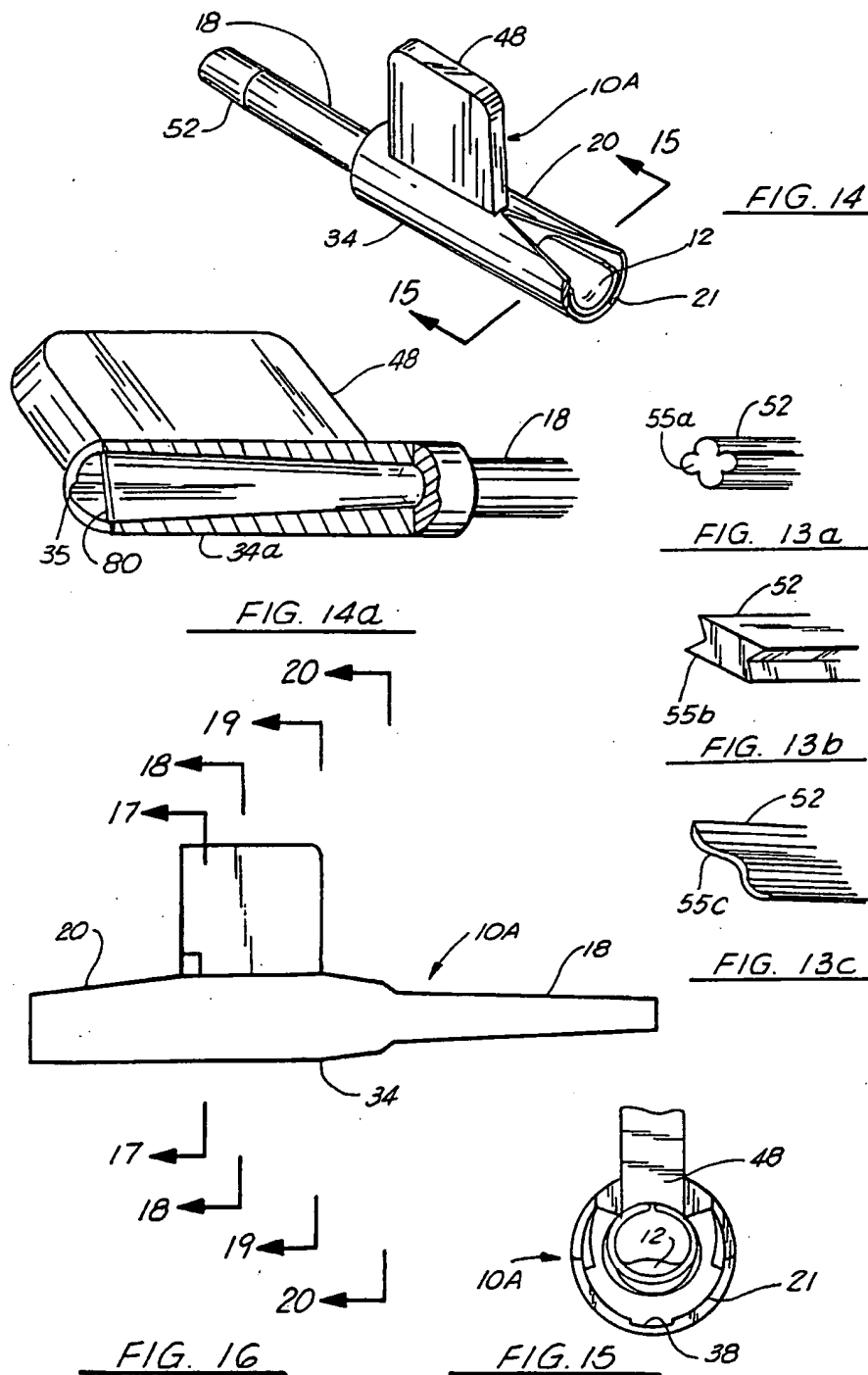


FIG. 11





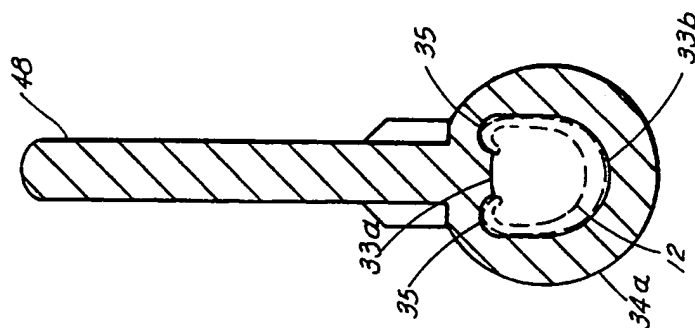


FIG. 17

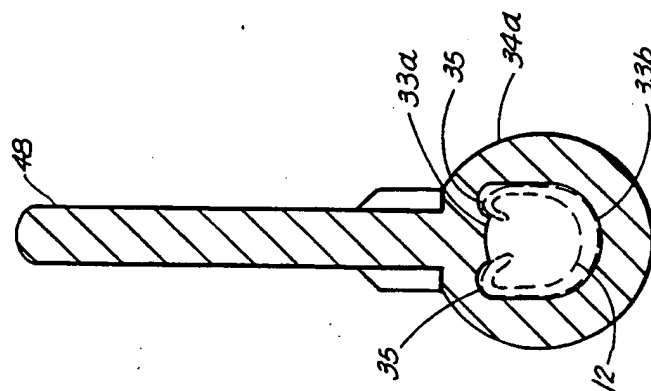


FIG. 18

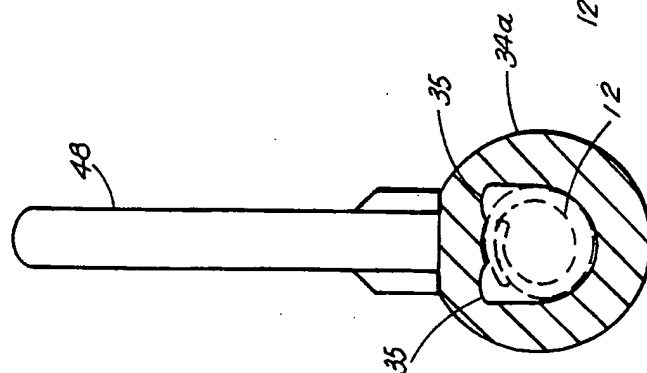


FIG. 19

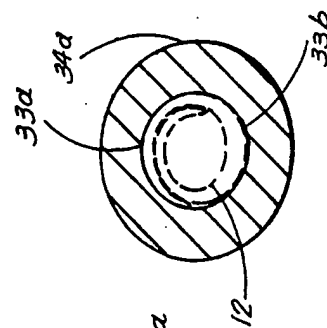
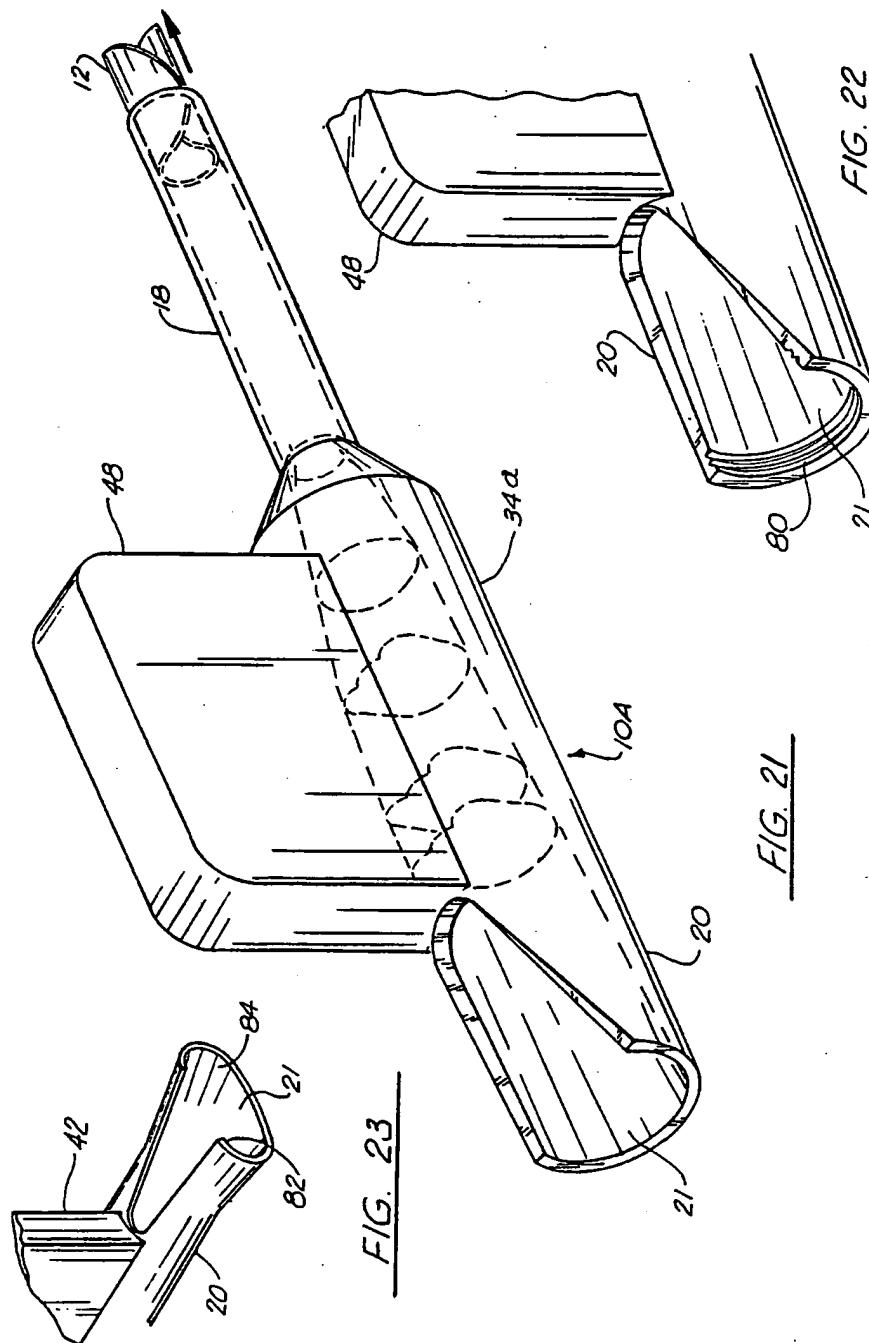


FIG. 20



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US94/02570

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/00

US CL :606/107

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/1, 107.1, 108 ; 623/4, 6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P ----- Y	US, A, 5,275,604, (RHEINISH ET AL.), 04 January 1994. See entire document.	1-4, 6, 7, 9-11, 17, 20, 30, 31- 37, 42, 45, 46, 55, 62, 67, 72- 75 ----- 5, 12, 13, 15, 21-24, 38, 44, 47, 49-51, 53, 63-66



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A" document defining the general state of the art which is not considered to be part of particular relevance	*X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E" earlier document published on or after the international filing date	*Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*&"	document member of the same patent family
*O" document referring to an oral disclosure, use, exhibition or other means		
*P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

05 MAY 1994

Date of mailing of the international search report

JUN 14 1994

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

GLENN KEITH DAWSON

Telephone No. (703) 308-4304

INTERNATIONAL SEARCH REPORT

In. ational application No.
PCT/US94/02570

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,123,905, (KELMAN), 23 June 1992. See entire document.	33-37, 40, 41, 48-51, 62, 71, 74, 75 ----- 38, 52-54, 66
X	US, A, 5,190,552, (KELMAN), 02 March 1993. See entire document.	33, 34, 39, 40, 45, 49, 50, 53, 54
X --- Y	US, A, 4,919,130, (STOY ET AL.), 24 April 1990. See entire document.	20-22, 30-37, 45, 49-51, 53, 55-57, 62-64, 74, 75 ----- 23, 24, 38, 52, 65, 66